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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,819	09/24/2003	Gerald Fredrickson	12013/49401	7313
23838	7590	06/21/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER

1762

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/670,819	Applicant(s) FREDRICKSON, GERALD	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, drawn to a method of coating, classified in class 427, subclass 2.24;
 - II. Claims 14-22, drawn to a coating apparatus, classified in class 118, subclass 300.
 - III. Claims 23-36, drawn to a medical device, classified in class 424, subclass 422.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such for coating drug capsules or small parts, such as nuts, bolts, or screws.
3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as dip-coating.

4. Inventions II and III are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product as claimed can be made by another and materially different apparatus, such as an immersion tank.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the others, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Brian Hennessey on 6/18/2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 14-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,368,658) in view of Park et al. (US2003/0230819 A1).

Schwarz teaches a method for coating medical devices, such as stents, by suspending the medical devices in a fluidizing gas flow and coating the medical devices with a coating provided by a nozzle(s) to inject an atomized coating material at a low velocity towards the medical devices (abstract; Figures; col. 9, lines 5-10; col. 13, lines 15-25). Schwarz teaches that the low velocity, atomized coating material is used so as not to disrupt the air flow and medical devices.

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While Schwarz teaches a nozzle sufficient to atomize a low velocity coating stream, he fails to specifically teach that the nozzle is an ultrasonic nozzle or that the vibration thereof is responsible for his atomization.

Park teaches a method of coating stents with atomized coatings, like Schwarz, and teaches that such atomization is created with the use of an ultrasonic nozzle and vibration thereof (P48; Example 7). Park attributes the popularity of ultrasonic nozzles in the biomedical field to the ability for to produce coating drops of low inertia. The velocity of an ultrasonic nozzle is said to be only 1-10% of an air-atomizing nozzle. The vibration used is minor enough that it will not harm bioactive substances (P51).

Since Schwarz teaches the use of low-velocity atomized spray-coating of stents in his air suspension coating system and Park teaches coating stents with low-velocity atomized coatings using an ultrasonic nozzle, Park would have reasonably suggested the use of an ultrasonic nozzle as the nozzle of Schwarz. It would have been obvious to one of ordinary skill in the art to use the teachings of Park in the method of Schwarz to provide Schwarz with a suitable nozzle for coating stents with his desired low-velocity, atomized coating spray. Examiner also notes that both Schwarz and Park desire coating stents with polymers and drugs in solution, so an ultrasonic nozzle is taught to be compatible with the types of coatings used by Schwarz (Schwarz: throughout; P113 of Park).

Regarding claims 2-3, Schwarz teaches the use of more than one fluidizing gas flows, which help direct the atomized coating to the medical appliance (col. 9 and throughout).

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Regarding claims 4-5, Park teaches a vibration at 60 kHz, lying within the range claimed by Applicant in claim 4, to achieve his desired coating droplet size, but fails to teach the specific 122 kHz of claim 5. However, Examiner notes that selection of kHz would have been within the skill of an ordinary artisan desiring to optimize droplet size.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

As required by claim 6, Schwarz teaches using fluidizing gas flow temperatures from 20-90 °C, most of which require heating of the fluidizing gas flow (col. 13, line 17).

Both references teach the inclusion of a therapeutic agent in the coating, as outlined above (col. 4 of Schwarz, for example), as required by claim 7.

Schwarz and Park coat stents. Specifically Schwarz shows approximately sixty stents being coating in the air suspension chamber of his invention, however Examiner considers this Figure to be merely exemplary. Schwarz also teaches a continuous coating, indicating that any number of stents can be manufactured by his process. Therefore it is Examiner's position that one of ordinary skill in the art would have been capable of selecting a desired number of stents to be coated in the method of Schwarz depending on consumer demand and size of the fluidization chamber.

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Stents are flexible to some degree which allows their movement through the vascular system, placement, and expansion.

Regarding claim 11, Schwarz teaches coating at 0.1-6 ml/min (col. 13, line 19).

Regarding claims 12-13, it appears that the air suspension device of Schwarz is a "hurricane". Additionally, page 2 of the instant specification teaches that the current air suspension methods in the art (which would be inclusive of Schwarz) use "hurricanes".

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "J. Kolb Michener".

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 19, 2004